REMARKS/ARGUMENTS

This paper is responsive to the Examiner's Final Office Action of July 29, 2008 and the Interview conducted with the Examiner on December 11, 2008. The Applicants would like to thank Examiner Deak for the in-person interview extended to Applicants' attorney of record, William H. Shreve, on December 11, 2008. Claims 1-6 and 46-72 are presently pending in this application. Reconsideration of the application in view of the foregoing amendments and following remarks is respectfully requested.

Claim Rejections and Amendments

The Examiner rejected Claims 1, 2, 4, 5, 46-49, 54 and 57 under 35 U.S.C. § 103(a) as being obvious in view of the combination of U.S. Patent No. 6,450,984 B1 to Lynch et al. ("Lynch") and U.S. Patent No. 5,980,928 to Terry ("Terry"); Claims 3 and 6 under 35 U.S.C. § 103(a) as being obvious in view of the combination of Lynch, Terry and U.S. Patent No. 7,033,603 B2 to Nelson et al. ("Nelson"); Claims 4, 5, 48-51, 53, 56, 58-60, 63-65 and 67-72 under 35 U.S.C. § 103(a) as being obvious in view of the combination of U.S. Patent No. 4,521,210 to Wong ("Wong") and Terry; Claims 1, 2, 4, 5, 46, 52, 54, 55 and 57 under 35 U.S.C. § 103(a) as being obvious in view of the combination of Lynch and U.S. Patent Application Publication No. 2005/0119737 A1 to Bene et al. ("Bene CIP"); and Claims 61, 62 and 66 under 35 U.S.C. § 103(a) as being obvious in view of the combination of Wong, Terry and Bene CIP.

Applicants respectfully traverse these rejections and the Examiner's characterization of the cited references on the bases set forth below. In this case, Claims 48, 58 and 64 have been amended, as shown above, to vary the scope of protection of Applicants' claimed invention, and not to overcome the prior art. These amendments are supported by the Application as originally filed, and no new matter has been introduced. Furthermore, Claim 67 has been amended to correct a typographical error and not for reasons related to patentability. Applicants reserve the right to pursue any of the prior versions of the claims in one or more continuing applications and/or at a later date.

Combination of Lynch and Terry is Improper

Applicants' respectfully submit that one of ordinary skill in the art would not generally combine the large implant designed for the eyelid to treat conjunctivitis disclosed in Terry with the small implant designed for implantation within internal eye tissue to increase fluid flow disclosed in Lynch.

First, the implant in Terry is temporary, whereas the implant in Lynch is permanent. Terry teaches an implant that provides for release of an antibiotic "over approximately a three to four month period." Terry, col. 2, lines 4-5. On the other hand, in the Summary of the Invention section, Lynch states that the "present invention is further directed to providing a permanent, indwelling shunt to provide increased egress of aqueous humor from the anterior chamber to Schlemm's canal for glaucoma management." Lynch, col. 5, lines 20-24.

Second, the implant in Terry is implanted external to the eye in the eyelid, whereas the implant in Lynch is implanted within the internal eye tissue. Terry discloses an implant that preferably "is implanted above the eye within the eyelid, approximately one half inch from the margin of the eyelid" to treat conjunctivitis in livestock. Terry, col.1, lines 66-67. Terry further teaches away from implantation in the eye by disclosing that the implant should be placed "in close proximity, but spaced from the eye 20 so as not to injure the eye 20." Terry, col. 4, lines 34-35. Lynch, on the other hand discloses a shunt device for implantation into the eye "to divert aqueous humor in the eye from the anterior chamber into Schlemm's canal, in which the shunt device comprises a distal portion having at least one terminal aspect sized and shaped to be circumferentially received within a portion of Schlemm's canal, and a proximal portion having at least one terminal aspect sized and shaped to be received within the anterior chamber of the eye." Col. 6, lines 50-60.

Third, the implant in Terry is comprised of antibiotic pellets embedded within a matrix material. The combination of Terry's antibiotic pellets with the shunt in Lynch would render the Lynch shunt generally inoperable for its disclosed intended purpose of shunting aqueous humor to relieve intraocular pressure. The large pellets of Terry would occlude the flow of aqueous humor from the anterior chamber to Schlemm's canal rather than promote fluid flow, as intended by Lynch.

Finally, as discussed with the Examiner in the Examiner Interview on December 11, 2008, the disclosure of such a large implant in Terry designed to be implanted in the eyelid is not

generally combinable with a small ocular implant **sized** and shaped to be received within internal eye tissue (on the microscopic level), such as Schlemm's canal. The sheer size of the Terry implant, if implanted within the eye, would not only damage the eye, but would occlude fluid flow instead of promoting fluid flow, as intended by Lynch.

For at least the foregoing reasons, one of ordinary skill in the art would not have combined Terry with Lynch. As such, the combination of Lynch and Terry is improper. Consequently, Applicants request that the instant § 103(a) rejections of Claims 1-6, 46-49, 54 and 57, which are based upon the combination of Lynch and Terry, be withdrawn. Regarding Claims 3 and 6, the addition of Nelson does not cure the deficiencies of the improper combination of Lynch and Terry.

Combination of Wong and Terry is Improper

As discussed in the Examiner Interview and stated in the *Examiner Interview Summary Report* prepared by the Examiner, "the disclosure of a large implant [in Terry] designed for the eyelid to treat conjunctivitis is not generally combinable with a small ocular implant as taught by the secondary references (Bene and Wong) and instantly claimed." The Examiner stated that she "tends to agree with this assessment." (page 3 of *Examiner Interview Summary Report* PTOL-413 dated December 11, 2008).

In addition, similar to Lynch, Wong teaches an implant intended for implantation within the eye and not the eyelid as disclosed in Terry.

Finally, a main focus of Wong is to provide an implant that is not prone to movement and provides unimpeded flow when implanted. Wong discloses background problems associated with known surgical procedures for relieving glaucoma. See column 6, lines 29-45. These include "motion of the implanted device over a period of time." While summarizing the implant device's structure and operation, Wong states at column 2, lines 26-32 (emphasis added):

> ... **to assure fixation** it is **preferably** of crucifix form, having a main stem portion extending along its length direction and a cross-arm transverse thereto **adapted to be sutured to the sclera** at a position between the angle at the periphery of the anterior chamber of the eye and the suprachoroidal space.

This disclosed permanent, anchoring focus of Wong is entirely absent in Terry, where the focus is on inserting a temporary implant "in a large group of animals during a short period of

time." Therefore, the main focus of Terry is to insert the implants into all the cattle in a particular corral area as quickly as possible. Since the Terry implants are temporary and eventually dissolve, anchoring is not of any concern, and there is no disclosure of an anchoring structure or function in Terry. The large size and temporary nature of the Terry implant renders it unsuitable for the disclosed intended purpose of the Wong implant.

Based on at least the foregoing reasons, one of ordinary skill in the art would not have combined Terry with Wong. As such, the combination of Wong and Terry is not *prima facie* obvious and is therefore improper. Consequently, Applicants request that the instant § 103(a) rejections of Claims 4, 5, 48-51, 53, 56 and 58-72 in view of Wong and Terry be withdrawn. With regard to Claims 61, 62 and 66, the addition of Bene does not cure the deficiencies of the improper combination of Wong and Terry.

Combination of Lynch and Bene is Improper

In order to simplify the discussion and for the Examiner's reference, Applicants include the following disclosure timeline for the relevant applications:

Application	Appl. No.	Filed	Publ. No.	Published
Lynch Provisional	60/131,030	4/26/99	N/A	N/A
Bene Provisional	60/175,658	1/12/00	N/A	N/A
Applicants' Parent Application	**09/549,350**	**4/14/00**	**6,638,239**	**10/28/03**
Lynch Patent	09/558,505	4/26/00	6,450,984	9/17/02
Bene PCT	PCT/US01/ 00350	1/5/01	WO 01/50493	7/19/01
Bene parent (National Stage Entry)	10/182,833	1/5/01	03/0212383	11/13/03
Applicants' Present Application	**10/760,300**	**11/12/03**	**04/0127843**	**7/1/04**
Bene CIP	10/857,452	6/1/04	05/0119737	6/2/05

TABLE 1: DISCLOSURE TIMELINE

The Examiner has used the combination of Lynch and Bene to reject independent Claims 1 and 4. As previously established, at least Claims 1 and 4 are supported by Applicants' priority U.S. Patent Application No. 09/549,350, filed April 14, 2000 (now U.S. Patent No. 6,638,239 B1). These claims thus are entitled to an effective filing date of April 14, 2000. Therefore, in order to predate the limitations of Claims 1 and 4, the cited Lynch and Bene patents must contain adequate written description support in the Lynch and Bene provisionals, respectively, for the subject matter relied upon by the Examiner in her rejection.

The Examiner stated in the most recent Office Action that the Lynch provisional fails to disclose an implant having a body comprising a therapeutic drug. Office Action, page 7. Therefore, the Examiner turns to the Bene CIP as teaching this claim limitation. Since the Bene CIP was filed after the Applicants' parent application, to which Claims 1 and 4 claim priority, the only way that the Bene CIP can be properly used as a prior art reference is if it can claim adequate written description support to the Bene provisional application for the subject matter relied upon for the rejection. Applicants submit that the Bene CIP fails in this regard.

Bene CIP Adds New Matter that Lacks Adequate Support in Bene Provisional

Applicants note that the Bene provisional lacks adequate § 112 support for the subject matter relied on by the Examiner for the instant § 103(a) rejections of Claims 1 and 4. As the Examiner well knows, a continuation-in-part application often adds new subject matter that does not have proper written description support in an earlier-filed application, and thus, the new subject matter is not entitled to the earlier filing date.

The Examiner has cited to the Bene CIP as disclosing "an ocular implant that may be coated, impregnated, or surround a therapeutic drug for delivery to the adjacent eye tissue (see at least paragraphs 0059-0061)." Office Action, page 7. This disclosure in the Bene CIP upon which the Examiner has relied was newly added in the CIP and does not have proper written description support in the Bene provisional. The Bene provisional instead discloses a device with an "anti infective or antibiotic agent . . . that prevents bacteria infiltration from the outside of the eye . . . and into the anterior chamber." (See, e.g., Section 7.A entitled "What the Invention Is and How It Works").

The Bene provisional discloses an embodiment of an implant formed of "a silicone, hyrdrogel or other flexible material" and that includes "a one valve [sic] to control the flow and a

[sic] anti infective agent compounded or coated on the device to prevent bacteria infiltration." (Section 7.E.6). The Bene provisional further discloses that "the invention as is could include drugs in the porous filter material, which would dissolve over time and be released into the eye." However, the Bene provisional fails to disclose the combination of drug delivery without the use of a porous filter material. Consequently, the portions of the Bene CIP cited to by the Examiner constitute new matter and cannot claim priority back to the Bene provisional.

As such, the Examiner cannot rely on Bene in combination with Lynch as disclosing each and every limitation of Claims 1 and 4. Accordingly, Applicants respectfully request that the instant § 103(a) rejections of Claims 1 and 4 in view of Lynch and Bene be withdrawn. Claims 2, 5, 46, 47, 52, 54 and 57 are nonobvious over the combination of Lynch and Bene for at least the same reasons as independent Claims 1 and 4, in addition to adding further limitations of their own. Accordingly, Applicants respectfully request that the instant § 103(a) rejections of Claims 2, 5, 46, 47, 52, 54 and 57 in view of Lynch and Bene be withdrawn.

Lynch Provisional Teaches Away from Use of Anti-Infective Agent of Bene

Even assuming, *arguendo*, that the Bene CIP does have adequate written support based on the Bene provisional, Applicants submit that one of ordinary skill in the art would not have been motivated to modify the aqueous shunt device from the Lynch provisional to include the anti-infective or antibiotic agent disclosed in the Bene provisional. The Background Section of the Lynch provisional describes aqueous shunt devices (such as the device of the Bene provisional) as a common filtering technique known to one of ordinary skill in the art for use in treating glaucoma. The Lynch provisional states that "[w]ith aqueous shunt devices, aqueous drains out of the eye through the silicone tube to the surface of the eye." (Page 6). The Lynch provisional further states that "[w]ith aqueous shunt devices, a pathway is created for bacteria to get into the eye and endophthalmitis can occur." (Page 7). In summarizing the problems with the prior art filtering procedures, including aqueous shunt devices such as the one disclosed in the Bene provisional, the Lynch provisional states:

> Most of the problems that have developed . . . have occurred because aqueous fluid is drained from inside of the eye to the surface of the eye. The purpose of this patent is to describe a number of devices and methods to enhance the drainage of aqueous fluid into Schlemm's canal and the anterior chamber angle.

(Page 7). The Lynch provisional goes on to state that "[e]nhancing aqueous flow directly into Schlemm's canal should eliminate complications such as endophthalmitis [caused by the influx of bacteria]." (Page 8). The Lynch provisional device is wholly contained within the interior of the eye and does not need to prevent against bacteria infiltration from the exterior of the eye. Therefore, the Lynch provisional clearly teaches away from the need for an anti-infective agent to prevent bacteria infiltration. Consequently, one of ordinary skill in the art would not have included the anti-infective agent to prevent bacteria infiltration disclosed in the Bene provisional with the Lynch shunt device because the anti-infective agent would be unnecessary.

Furthermore, a main focus of the Lynch provisional disclosure regarding the shunt device is to provide a device to maximize the outflow of aqueous humor from the anterior chamber to Schlemm's canal without obstruction or occlusion. The Lynch provisional clearly teaches away from placing any structure, such as a valve or porous filter as taught by Bene, within the disclosed shunt device and states at page 11, approx. lines 8-9 (emphasis added):

> The device is composed of an inert, flexible material such as silicone. The material is fashioned into a t-bar shape that is **completely hollow**.

Thus, the Lynch provisional device is geared toward providing **dynamic fluid outflow** from the anterior chamber to Schlemm's canal. The Lynch provisional also discloses treatment using a balloon catheter to administer a drug in a single bolus to avoid dilution of the drug. On the other hand, in the Bene provisional, the device is coated or compounded with an anti-infective agent that slowly releases the anti-infective agent into the immediate area of the device to treat a limited volume of relatively **stagnant** aqueous humor. In order to create this relatively stagnant condition, the Bene provisional device either incorporates a porous structure to provide a tortuous path through the device or incorporates a valve to restrict flow. Under conditions of high flow, the slow release rate of drug from the Bene device would cause the anti-infective agent to be diluted. Therefore, modifying the Lynch provisional device by coating it or compounding an anti-infective agent into it, as disclosed in the Bene provisional, would have been contradictory to the teaching against the dilution of drugs administered in connection with the device in the Lynch provisional.

At least for these reasons, Applicants submit that the Examiner's combination of the shunt device disclosed in the Lynch provisional and the anti-infective agent of the Bene provisional is improper. Accordingly, Applicants respectfully request that the instant § 103(a) rejections of Claims 1 and 4 in view of Lynch and Bene be withdrawn. Claims 2, 5, 46, 47, 52, 54 and 57 are nonobvious over the combination of Lynch and Bene for at least the same reasons as independent Claims 1 and 4, and because each recites a novel and non-obvious combination of elements. Accordingly, Applicants respectfully request that the instant § 103(a) rejections of Claims 2, 5, 46, 47, 52, 54 and 57 in view of Lynch and Bene be withdrawn.

No Disclaimers or Disavowals

Although the present communication includes alterations to the claims and characterizations of claim scope and referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Related Cases

In addition to the Amendments and Remarks provided above, Applicants wish to draw the Examiner's attention to the following U.S. issued patents and co-pending patent applications that may be related to Applicants' present application:

Attorney Docket No.	Appl. No. (Patent No.)	Filing Date	Title
GLAUKO.1C2C3	10/889,254	12-Jul-2004	GLAUCOMA IMPLANT WITH BI-DIRECTIONAL FLOW
GLAUKO.1C3CP2	11/126,868	11-May-2005	INJECTABLE GEL IMPLANT FOR GLAUCOMA TREATMENT
GLAUKO.1C4C10	11/841,967	20-Aug-2007	THERAPEUTIC SHUNT DEVICE AND METHOD FOR TREATING GLAUCOMA

Attorney Docket No.	Appl. No. (Patent No.)	Filing Date	Title
GLAUKO.011C1	11/598,542	13-Nov-2006	IMPLANTS AND METHODS THEREOF FOR TREATMENT OF OCULAR DISORDERS
GLAUKO.011CP1	10/634,213	05-Aug-2003	DEVICES AND METHODS FOR GLAUCOMA TREATMENT
GLAUKO.11CP1C1	11/836,106	08-Aug-2007	DEVICES AND METHODS FOR GLAUCOMA TREATMENT
GLAUKO.11CP1C2	11/836,112	08-Aug-2007	DEVICES AND METHODS FOR GLAUCOMA TREATMENT
GLAUKO.011CP2	10/695,668	28-Oct-2003	GLAUCOMA TREATMENT KIT
GLAUKO.11CP2CP1	11/084,314	18-Mar-2005	INJECTABLE GLAUCOMA IMPLANTS WITH MULTIPLE OPENINGS
GLAUKO.011CP3	11/083,713	18-Mar-2005	GLAUCOMA IMPLANTS WITH ANCHORS
GLAUKO.013A	10/139,800 (7,094,225)	03-May-2002	MEDICAL DEVICE AND METHODS OF USE FOR GLAUCOMA TREATMENT
GLAUKO.013C1	11/255,625 (7,273,475)	21-Oct-2005	MEDICAL DEVICE AND METHODS OF USE FOR GLAUCOMA TREATMENT
GLAUKO.013C1DV1	11/860,785	25-Sep-2007	OCULAR IMPLANT WITH DOUBLE ANCHOR MECHANISM
GLAUKO.020A	10/384,912 (7,186,232)	07-Mar-2003	FLUID INFUSION METHODS FOR GLAUCOMA TREATMENT
GLAUKO.020C1	11/332,746	12-Jan-2006	FLUID INFUSION METHODS FOR GLAUCOMA TREATMENT
GLAUKO.022C1	11/653,815	16-Jan-2007	COMBINED TREATMENT FOR CATARACT AND GLAUCOMA TREATMENT
GLAUKO.034A	10/662,696 (7,192,412)	15-Sep-2003	TARGETED STENT PLACEMENT AND MULTI-STENT THERAPY
GLAUKO.035A	10/667,580	22-Sep-2003	GLAUCOMA IMPLANT AND DELIVERY SYSTEM
GLAUKO.099A	11/938,238	09-Nov-2007	UVEOSCLERAL SHUNT AND METHODS FOR IMPLANTING SAME

Copies of the patents, applications, and pending claims, including any office actions and allowances, are available through PAIR. However, if the Examiner so requests, Applicants will be happy to provide the Examiner with copies of any patents, applications, pending claims, office actions, allowances, or any other documents, at any time.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance in view of the above remarks. Any remarks in support of patentability of one claim, however, should not be imputed to any other claim, even if similar terminology is used. Additionally, any remarks referring to only a portion of a claim should not be understood to base patentability on that

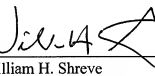
portion; rather, patentability must rest on each claim taken as a whole. Applicants respectfully traverse each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Rather, the amendments are made only to expedite prosecution of the present application, and without prejudice to presentation or assertion, in the future, of claims on the subject matter affected thereby.

Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly. Also, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Dec 23, 2008

By: 

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